PATENT COOPERATION TREATY

From the
INTERNATIONAL SEARCHING AUTHORITY

To:

see form PCT/ISA/220

PCT

WRITTEN OPINION OF THE INTERNATIONAL SEARCHING AUTHORITY

(PCT Rule 43*bis*.1)

Date of mailing
(day/month/year) see form PCT/ISA/210 (second sheet)

Applicant's or agent's file reference
see form PCT/ISA/220

FOR FURTHER ACTION
See paragraph 2 below

International application No.	International filing date *(day/month/year)*	Priority date *(day/month/year)*
PCT/IL2004/001166	23.12.2004	29.12.2003

International Patent Classification (IPC) or both national classification and IPC
A61B5/00

Applicant
GLUCON INC.

1. This opinion contains indications relating to the following items:

- ☒ Box No. I Basis of the opinion
- ☐ Box No. II Priority
- ☒ Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- ☒ Box No. IV Lack of unity of invention
- ☒ Box No. V Reasoned statement under Rule 43*bis*.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- ☐ Box No. VI Certain documents cited
- ☐ Box No. VII Certain defects in the international application
- ☐ Box No. VIII Certain observations on the international application

2. **FURTHER ACTION**

If a demand for international preliminary examination is made, this opinion will usually be considered to be a written opinion of the International Preliminary Examining Authority ("IPEA"). However, this does not apply where the applicant chooses an Authority other than this one to be the IPEA and the chosen IPEA has notifed the International Bureau under Rule 66.1*bis*(b) that written opinions of this International Searching Authority will not be so considered.

If this opinion is, as provided above, considered to be a written opinion of the IPEA, the applicant is invited to submit to the IPEA a written reply together, where appropriate, with amendments, before the expiration of three months from the date of mailing of Form PCT/ISA/220 or before the expiration of 22 months from the priority date, whichever expires later.

For further options, see Form PCT/ISA/220.

3. For further details, see notes to Form PCT/ISA/220.

Name and mailing address of the ISA:

European Patent Office
D-80298 Munich
Tel. +49 89 2399 - 0 Tx: 523656 epmu d
Fax: +49 89 2399 - 4465

Authorized Officer

Willig, H

Telephone No. +49 89 2399-7464

WRITTEN OPINION OF THE INTERNATIONAL SEARCHING AUTHORITY

International application No.
PCT/IL2004/001166

Box No. I Basis of the opinion

1. With regard to the **language**, this opinion has been established on the basis of the international application in the language in which it was filed, unless otherwise indicated under this item.

   ☐ This opinion has been established on the basis of a translation from the original language into the following language , which is the language of a translation furnished for the purposes of international search (under Rules 12.3 and 23.1(b)).

2. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application and necessary to the claimed invention, this opinion has been established on the basis of:

   a. type of material:

   ☐ a sequence listing

   ☐ table(s) related to the sequence listing

   b. format of material:

   ☐ in written format

   ☐ in computer readable form

   c. time of filing/furnishing:

   ☐ contained in the international application as filed.

   ☐ filed together with the international application in computer readable form.

   ☐ furnished subsequently to this Authority for the purposes of search.

3. ☐ In addition, in the case that more than one version or copy of a sequence listing and/or table relating thereto has been filed or furnished, the required statements that the information in the subsequent or additional copies is identical to that in the application as filed or does not go beyond the application as filed, as appropriate, were furnished.

4. Additional comments:

Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability

The questions whether the claimed invention appears to be novel, to involve an inventive step (to be non obvious), or to be industrially applicable have not been examined in respect of:

☐ the entire international application,

☒ claims Nos. 5-7, 8-24 as far as dependent on claims Nos. 5-7

because:

☐ the said international application, or the said claims Nos. relate to the following subject matter which does not require an international preliminary examination *(specify)*:

☐ the description, claims or drawings *(indicate particular elements below)* or said claims Nos. are so unclear that no meaningful opinion could be formed *(specify)*:

☐ the claims, or said claims Nos. are so inadequately supported by the description that no meaningful opinion could be formed.

☒ no international search report has been established for the whole application or for said claims Nos. 5-7, 8-24 as far as dependent on claims Nos. 5-7

☐ the nucleotide and/or amino acid sequence listing does not comply with the standard provided for in Annex C of the Administrative Instructions in that:

the written form	☐	has not been furnished
	☐	does not comply with the standard
the computer readable form	☐	has not been furnished
	☐	does not comply with the standard

☐ the tables related to the nucleotide and/or amino acid sequence listing, if in computer readable form only, do not comply with the technical requirements provided for in Annex C-*bis* of the Administrative Instructions.

☐ See separate sheet for further details

Box No. IV Lack of unity of invention

1. ☒ In response to the invitation (Form PCT/ISA/206) to pay additional fees, the applicant has:

   ☐ paid additional fees.

   ☐ paid additional fees under protest.

   ☒ not paid additional fees.

2. ☐ This Authority found that the requirement of unity of invention is not complied with and chose not to invite the applicant to pay additional fees.

3. This Authority considers that the requirement of unity of invention in accordance with Rule 13.1, 13.2 and 13.3 is

   ☐ complied with

   ☒ not complied with for the following reasons:

   see separate sheet

4. Consequently, this report has been established in respect of the following parts of the international application:

   ☐ all parts.

   ☒ the parts relating to claims Nos. 1-4, parts of claims Nos. 8-24

Box No. V Reasoned statement under Rule 43*bis*.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Yes:	Claims	1-4, 8-24 as far as dependent on claims 1-4
	No:	Claims	
Inventive step (IS)	Yes:	Claims	1-4, 8-24 as far as dependent on claims 1-4
	No:	Claims	
Industrial applicability (IA)	Yes:	Claims	1-4, 8-24 as far as dependent on claims 1-4
	No:	Claims	

2. Citations and explanations

   see separate sheet

Reference is made to the following documents:
D1: EP-A-1 048 265

Re Item IV

The application contains the following two inventions as indicated in the international search report.

Claims 1-4, parts of **claims 8-24** (invention 1):
Apparatus for assaying an analyte in a body in which the concentration of the analyte is determined based on the measurement of acoustic phenomena originating from photoacoustic stimulation processes.

Claims 5-7, parts of **claims 8-24** (invention 2):
Apparatus for assaying an analyte in a body in which the concentration of the analyte is determined based on the measurement of the absorption of light.

Both inventions determine the concentration of the analyte based on the absorption of light by the analyte with the light source being implantable into the body. This concept is commonly known in the state of the art, for instance from the publication by Martin, W. B. et al. cited in the application on p. 2, l. 28 to p. 3, l. 8.

The contribution of the first invention over the state of the art by Martin et al. resides in the use of photoacoustic stimulation processes for the determination of the analyte concentration. Effects having their origin in photoacoustic stimulation processes are measured with an acoustic sensing transducer externally coupled to the body. Accordingly, the concentration of the analyte can be determined even if the light emitted from the implanted light source is completely absorbed in the body.

The contribution of the second invention over the state of the art by Martin et al. resides in a fully implanted light source and light detector combination for the determination of the analyte concentration. Light absorption effects are directly measured within the body. Accordingly, the concentration of the analyte can be determined without the use of external sensors.

Therefore, the two inventions do not involve same or corresponding special technical features and, thus, there is no technical relationship between them in the sense of Rule 13.2 PCT. Consequently, the two inventions are not so linked as to form a single general inventive concept as required by Rule 13.1 PCT.

Re Item V

Document D1 can be considered as closest prior art for the subject-matter of the 1st invention as defined in independent **claims 1**, **3** and **4**. It discloses an apparatus for detecting an analyte in a body and measuring its concentration comprising a light source (4, 5) and an acoustic detector (3, 6). The acoustic detector is for the detection of acoustic signals originating from the absorption of light, i.e. the detection and the measuring base on the photoacoustic effect.

The common difference of the apparatuses of independent **claims 1**, **3** and **4** to the known apparatus is that the light source is implantable.

With an implanted light source the area where the photoacoustic effects are stimulated remains the same for each measurement. This improves the reliability of the determination of the analyte concentration and, at the same time, facilitates the use of the apparatus.

In the available prior art documents, the use of an implantable light source for the determination of the concentration of an analyte in a body based on photoacoustic effects is not disclosed. Therefore, **claims 1-4** and **claims 8-24** as far as the latter ones are dependent on **claims 1-4** are considered to meet the requirements of Art. 33(2)-(4) PCT.